IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	*	MDL Docket No. 2004 4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*	
LIABILITY LITIGATION	*	Case No. 4:13-cv-229 (Burke)

O R D E R

Plaintiff Vivian Burke filed this action on June 4, 2013 by filing a short form complaint in *In Re: Coloplast Corp. Pelvic Support System Products Liability Litigation*, MDL No. 2387. On September 13, 2016, the Court issued an order transferring the action to the United States District Court for the Southern District of Texas. That order (ECF No. 55 in 4:13-cv-229) is hereby vacated. The Court erroneously treated Burke's case as one that had been filed directly in this MDL under the Court's direct filing order. But it was not; it was filed in MDL No. 2387 and transferred to this Court for pretrial proceedings by the Judicial Panel on Multidistrict Litigation. Thus, the proper procedure is for the Court to suggest remand to the United States District Court for the Southern District of West Virginia, which is where this action originated. If the parties wish to seek transfer to the United States District Court for the Southern District of Texas, they should do so after this action is remanded.

Upon completion of the pretrial proceedings in this action, the parties did not agree to a waiver of venue under *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). The Court thus cannot conduct the trial of this action in the United States District Court for the Middle District of Georgia. The Court thus suggests that this action be remanded to the United States District Court for the Southern District of West Virginia. This Order contains a brief chronicle of the coordinated proceedings to provide guidance to that court.

I. Brief Background of the Mentor ObTape MDL

Mentor Worldwide LLC manufactured and sold a polypropylene mesh suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. The United States Food and Drug Administration cleared ObTape for sale in 2003 via its 510(k) regulatory process, and ObTape remained on the market in the United States until March 2006.

Several years ago, women who had been surgically implanted with ObTape began filing lawsuits against Mentor, alleging that they had been injured by ObTape—primarily that they suffered infections caused by ObTape and that they were injured when ObTape eroded through their bodily tissues. In December 2008, the Judicial Panel on Multidistrict Litigation created MDL No. 2004 and transferred seventeen actions involving alleged

injuries resulting from ObTape to this Court for consolidated and coordinated pretrial proceedings. *See In re Mentor Corp. ObTape Transobturator Sling Products Liability Litigation*, 588 F. Supp. 2d 1374 (J.P.M.L. 2008). After pretrial proceedings and a bellwether trial that settled mid-trial, the original cases and approximately forty additional tag-along cases transferred to this Court were resolved through settlement. Since then, MDL No. 2004 has grown to include more than 800 additional tag-along cases, more than 200 of which remain open. The litigation was divided into phases, and cases from phases IV and V are still pending. In 2013, the Court tried a Phase III bellwether case to verdict. In 2016, the Court tried a Phase IV-1 bellwether case to verdict.

II. Overview of Burke's Case

Plaintiff Vivian Burke alleges that she suffered various injuries that she attributes to ObTape. Burke filed her Complaint in this action on June 4, 2013. This action was designated as a Phase IV-6 case. Discovery closed in June 2016. On September 2, 2016, the Court granted Mentor's motion for partial summary judgment. The following counts remain pending: I - negligence; II - strict liability – design defect; III – strict liability – manufacturing defect; XIV - gross negligence; and XVII - punitive damages. All common discovery and coordinated pretrial proceedings in this case are complete, and

the case is ready for trial. Mentor and Burke declined to consent to trial in the Middle District of Georgia.

CONCLUSION

As discussed above, the Court suggests that this action be remanded to the United States District Court for the Southern District of West Virginia. For the convenience of that court, the Court compiled a list of significant filings and orders in this case and in MDL No. 2004. That list appears as an appendix to this Order.

The Clerk of Court is directed to provide a copy of this Order to the Clerk of the Judicial Panel on Multidistrict Litigation.

IT IS SO ORDERED, this 14th day of September, 2016.

S/Clay D. Land
CLAY D. LAND
CHIEF UNITED STATES DISTRICT COURT JUDGE
MIDDLE DISTRICT OF GEORGIA

APPENDIX

Significant filings and orders in this case and in MDL No. 2004:

I. Significant Filings Specific to Burke

1. Plaintiff Vivian Burke's Complaint, June 4, 2013. ECF No. 1 in 4:13-cv-229.

2. Answer to Burke's Complaint, with Jury Demand, July 29, 2013. ECF No. 12 in 4:13-cv-229.

3. Order granting Mentor's partial summary judgment motion. Sept. 2, 2016. ECF No. 51 in 4:13-cv-229.

4. Notice Regarding *Lexecon*, Sept. 9, 2016. ECF No. 53 in 4:13-cv-229. States that Mentor does not agree to waive *Lexecon*.

5. Notice Regarding *Lexecon*, Sept. 9, 2016. ECF No. 54 in 4:13-cv-229. States that Burke does not agree to waive *Lexecon*.

II. Other Relevant Filings

These filings are, for the most part, evidentiary rulings that were made in the context of the bellwether cases that were tried in this Court; these issues may arise again.

1. Order Denying Motion to Disqualify Expert Witness Dr. Catherine Ortuno, Apr. 1, 2010. ECF No. 231 in 4:08-md-2004; 2010 WL 1416548.
   Summary: Mentor sought to exclude the testimony of Dr. Catherine Ortuno, who was an employee of a French Mentor subsidiary called Porges. While she was employed by Porges, Dr. Ortuno and a colleague developed concerns about the safety of ObTape and ultimately recommended that sales of ObTape be stopped. The Court concluded that Dr. Ortuno would be permitted to serve as an expert witness for Plaintiffs but that she would not be permitted to offer any testimony that would divulge privileged, attorney-client communications.

2. Order on Phase I Summary Judgment Motions and Admissibility of Plaintiffs' Experts, Apr. 22, 2010. ECF No. 241 in 4:08-md-2004; 711 F. Supp. 2d 1348.
Summary: Mentor sought to exclude Plaintiffs' experts under Federal Rule of Evidence 702.
Dr. Catherine Ortuno – motion denied; the Court found that Dr. Ortuno's methodology was sufficiently reliable.
General Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. Michel Cosson, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, Dr. Donald Ostergard, Dr. William Porter, and Dr. Andrew Siegel) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
Specific Causation Witnesses (Dr. Linda Brubaker, Dr. Suzanne Bush, Dr. John Davis, Dr. James Hiller, Dr. Mickey Karram, Dr. Kenneth Mitchell, and Dr. Mark Slack) – motion denied; the Court found that these experts' methodology was sufficiently reliable.
Dr. George Samaras – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Samaras would be permitted to testify on general causation but not specific causation.
Dr. Ahmed El-Ghannam – motion denied; the Court found that Dr. El-Ghannam's opinions were sufficiently reliable.
Dr. Paul Ducheyne – motion granted in part and denied in part; based on then-existing Rule 26 Report, the Court concluded that Dr. Ducheyne could not testify regarding what caused degradation in ObTape but could testify that Mentor should have done more testing based on Mentor's awareness that ObTape could degrade.
Dr. Arnold Lentnek – motion deferred pending *Daubert* hearing. On May 12, 2010, the Court decided to permit Dr. Lentnek's testimony (ECF No. 301 in 4:08-md-2004).

3. Order re Evidence Related to FDA Regulatory Process, Apr. 23, 2010. ECF No. 242 in 4:08-md-2004; 2010 WL 1734638.
Summary: Plaintiffs sought to exclude evidence related to the FDA regulatory process. Discussed basic rules regarding evidence of FDA regulatory process. Deferred ruling until pretrial conference. At the pretrial conference on May 3, 2010, the Court granted the motion in limine but stated that if Plaintiffs

opened the door to the FDA evidence, it could come in. (ECF No. 299 – Transcript 174:9-175:16).

Note: the Court admitted 510(k) evidence during the 2013 trial of *Morey v. Mentor*, 4:11-cv-5065 but gave a limiting instruction on this issue. *Morey*, Jury Instructions Charge No. 11, ECF No. 183 in 4:11-cv-5065. But the Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.

4. Order re Phase I Plaintiffs' Experts, Apr. 27, 2010. ECF No. 246 in 4:08-md-2004; 2010 WL 1727828.
Summary: Mentor sought to exclude the testimony of Plaintiffs' experts under Federal Rule of Evidence 702 and based on relevance. The motion was granted in part and denied in part.
Dr. Ann Buchholtz – testimony not permitted.
Rabbit Study – testimony explaining rabbit study permitted, but not testimony that rabbit study establishes that ObTape is capable of causing similar conditions in humans.
Mentor's Warnings to Physicians and the FDA – testimony may be relevant to failure to warn claim, but Plaintiff must establish relevance before eliciting this testimony.

5. Order re Phase I Experts, Apr. 29, 2010. ECF No. 282 in 4:08-md-2004; 2010 WL 1782272.
Summary: The parties sought to exclude expert testimony of each other's experts under Federal Rule of Evidence 702. The motions were denied.
Dr. Michael Chernick (Plaintiffs' statistician) – testimony permitted.
Mentor's Specific Causation Rebuttal Witnesses (Dr. Marta Villarraga, Dr. Charles L. Secrest, Dr. A.W. Karchmer, Dr. James M. Anderson) – testimony permitted.
Dr. Marta Villarraga (Mentor's expert re Mentor's conduct in bringing ObTape to Market) – testimony permitted.
Mentor's Experts regarding Pore Distribution **(**Drs. Villarraga and Clevenger) – testimony permitted.

6. Phase I Bellwether Pretrial Conference Transcript (Day 1), May 3, 2010. ECF No. 299 in 4:08-md-2004. Ruled

from the bench on several motions in limine.
Significant Issues:

- Cross Motions to Exclude Evidence re FDA Regulatory Process (ECF Nos. 249 & 259) – Granted. Hr'g Tr. 164:11-175:16. Written opinion on this issue December 3, 2015. *See infra* § III.18.i.
- Plaintiffs' Motion to Exclude "Complication Rates" (ECF Nos. 250 & 251) – Denied. Hr'g Tr. 175:20-178:19.

7. Phase I Bellwether Pretrial Conference Transcript (Day 2), May 4, 2010. ECF No. 300 in 4:08-md-2004. Ruled from the bench on several motions in limine.
Significant Issue:
Mentor's Motion to Exclude Evidence Adverse Event Reports (ECF No. 273) – Denied, but reports must be redacted. Hr'g Tr. 42:7-47:8.

8. Order re Dr. Arnold Lentnek, May 12, 2010. ECF No. 301 in 4:08-md-2004.
Summary: Denied Mentor's motion to exclude Dr. Lentnek, concluding that Dr. Lentnek's methodology was sufficiently reliable.

9. Order to "Tie Up Some Loose Ends" after Pretrial Conference, May 18, 2010. ECF No. 335 in 4:08-md-2004, 2010 WL 1998166.
Summary: addressed several issues. Significantly, the Court stated that it would permit recording of the testimony of European witnesses so the recordings could be used in later trials of MDL No. 2004 cases. Also addressed the trial structure and concluded that trial should be bifurcated (Phase 1: compensatory damages/punitive damages entitlement; Phase 2: punitive damages amount).

Note: part of this Order was later vacated (*see* ECF 350 re continuing duty to warn under Georgia law).

10. Order re Subsequent Remedial Measure, May 20, 2010. ECF No. 341 in 4:08-md-2004, 2010 WL 2015146.
Summary: Concluded that Mentor's decision to stop selling ObTape is a subsequent remedial measure under Federal Rule of Evidence 407, so evidence of this decision is not admissible "to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or

instruction" but may be admitted for another purpose. Also concluded that Mentor's introduction of a new sling product, Aris, was *not* a subsequent remedial measure under Federal Rule of Evidence 407.

11. Order re Similar Complications, May 28, 2010. ECF No. 351 in 4:08-md-2004, 2010 WL 2196632.
Summary: Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

12. Order Appointing Plaintiffs' Liaison Counsel and Co-Lead Counsel, Sept. 21, 2011. ECF No. 422 in 4:08-md-2004.

13. Order Establishing Plaintiffs' Litigation Expense Fund and Common Benefit, Aug. 9, 2012. ECF No. 493 in 4:08-md-2004. This agreement is between Plaintiffs' counsel and addresses the sharing among Plaintiffs of the cost of special services performed and expenses performed for the common benefit of the Plaintiffs of MDL No. 2004.

14. Text Order re Dr. Ahmed El-Ghannam, June 4, 2013 in *Morey v. Mentor*, 4:11-cv-5065. Explained that general causation witness's must be tied to the Plaintiff: "To introduce [Dr. El-Ghannam'] testimony regarding ObTape degradation and/or the release of toxins, the witness must establish a causal connection between that degradation and/or release of toxins and Plaintiff's infection and extrusion/erosion."

15. Order re Post-Injury Evidence/Punitive Damages (in *Morey v. Mentor*), June 12, 2013. ECF No. 671 in 4:08-md-2004.
Summary: Concluded that, under Minnesota law, certain post-injury evidence is admissible on the issue of punitive damages.

16. Order re Withdrawal of ObTape from the Market (in *Morey v. Mentor*), June 12, 2013. ECF No. 673 in 4:08-md-2004.
Summary: Reiterated that the withdrawal of ObTape from the market was a subsequent remedial measure under Federal Rule of Evidence 407.

17. Jury Instructions and verdict form in *Morey v. Mentor*, June 13, 2013. ECF No. 183 in 4:11-cv-5065. **Notes:** Morey asserted a negligence claim under Minnesota law. The Court reconsidered its ruling on the admissibility of FDA 510(k) evidence in its order on Phase IV-1 motions in limine dated December 3, 2015.
18. Order on Motions in Limine, Dec. 3, 2015 (in *Taylor*, 4:12-cv-176; *Sanborn*, 4:13-cv-42; and *Mack*, 4:14-cv-117), ECF No. 92 in 4:12-cv-176, 2015 WL 7863032.

Significant issues:

i. **FDA 510(k) Evidence.** Ruled that evidence of 510(k) preclearance process would not be admitted because even if it is relevant, the probative value is substantially outweighed by the risk of unfair prejudice and potential to confuse and mislead the jury.

ii. **Dr. Lentnek.** Ruled that Plaintiffs would have to establish "fit" prior to admission of Dr. Lentnek's testimony.

iii. **Dr. El-Ghannam.** Ruled that Plaintiffs would have to make proffer of specific causation before Dr. El-Ghannam could testify on certain issues.

iv. **Post-Implant Evidence.** Ruled that evidence of Mentor's conduct and awareness after Plaintiffs' implant date is admissible.

19. Order re Similar Complications (in *Taylor*, 4:12-cv-176; *Sanborn*, 4:13-cv-42; and *Mack*, 4:14-cv-117), Feb. 1, 2016. ECF No. 115 in 4:12-cv-176, 2016 WL 393958. **Summary:** Explained rationale for concluding that other incidents of ObTape complications proffered by Plaintiffs were substantially similar to Plaintiffs' injuries.

20. Jury Instructions and verdict form in *Taylor v. Mentor*, Feb. 18, 2016. ECF Nos. 172, 174 in 4:12-cv-176. **Note:** Taylor's claims were under Florida law.